4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0030]

Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* on February 28, 2022. The document announced the withdrawal of approval of five abbreviated new drug applications (ANDAs) from multiple applicants as of March 30, 2022. The document indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, Venus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540: ANDA 091008, Gabapentin Capsules, 100 milligrams (mg), 300 mg, and 400 mg. Before FDA withdrew the approval of this ANDA, Jiangsu Hengrui Pharmaceuticals Co., Ltd., informed FDA that it did not want the approval of the ANDA withdrawn. Because Jiangsu Hengrui Pharmaceuticals Co., Ltd., timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 091008 is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of February 28, 2022 (87 FR 11079), appearing on page 11079 in FR Doc. 2022-04153, the following correction is made:

On page 11079, in the table, the entry for ANDA 091008 is removed.

Dated: April 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-08299 Filed: 4/18/2022 8:45 am; Publication Date: 4/19/2022]